

## **REMARKS**

Claims 20-29 were previously pending. No claims have been added or canceled. Reconsideration of pending claims 20-29 in light of the following remarks is respectfully requested.

### **§103 Rejections**

**Claim 20** stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,063,088 to Winslow (“Winslow”) in view of U.S. Patent No. 6,238,435 to Meulink et al. (“Meulink”). Applicants respectfully traverse this rejection on the grounds that these references are defective in establishing a prima facie case of obviousness with respect to claim 20.

As the PTO recognizes in MPEP § 2142:

*... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...*

It is submitted that the examiner has not factually supported a prima facie case of obviousness in the present case.

In the current case, even when combined Winslow and Meulink do not teach the combination of elements recited in claim 20. Independent claim 20 requires, “providing an implantation device adjacent to the alignment instrument via a clamp assembly operatively connected to the alignment instrument, the implantation device holding the prosthetic device at a distal end thereof.” In this regard, the Examiner recognized that Winslow fails to disclose a clamp assembly as explicitly required by claim 20. However, the Office Action asserts that “Meulink et al. disclose a clamp assembly to operatively connect the alignment instrument and implantation device, towards a distal end... It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Winslow having at least a clamp assembly in view of Meulink et al. to better orient the alignment device relative to the prosthetic device.” Applicants respectfully disagree.

First, Applicants disagree with the characterization of the “L-shaped pivot block 36” of Meulink as being a clamp assembly. There is no indication in Meulink that the pivot block 36 is capable of clamping onto anything. Rather, “[t]he pivot block 36 is connected to the stationary handle 22 via a connecting link 38 pinned at one end to the pivot block 36 to form a fulcrum 40 and pinned 42 at the other end to a mounting ring 44 affixed to the stationary handle 22.” The pivot block 36 simply does not clamp onto anything. Rather, the pivot block 36 and its fulcrum 40 serve to generate a mechanical advantage for the assembly of modular implants.

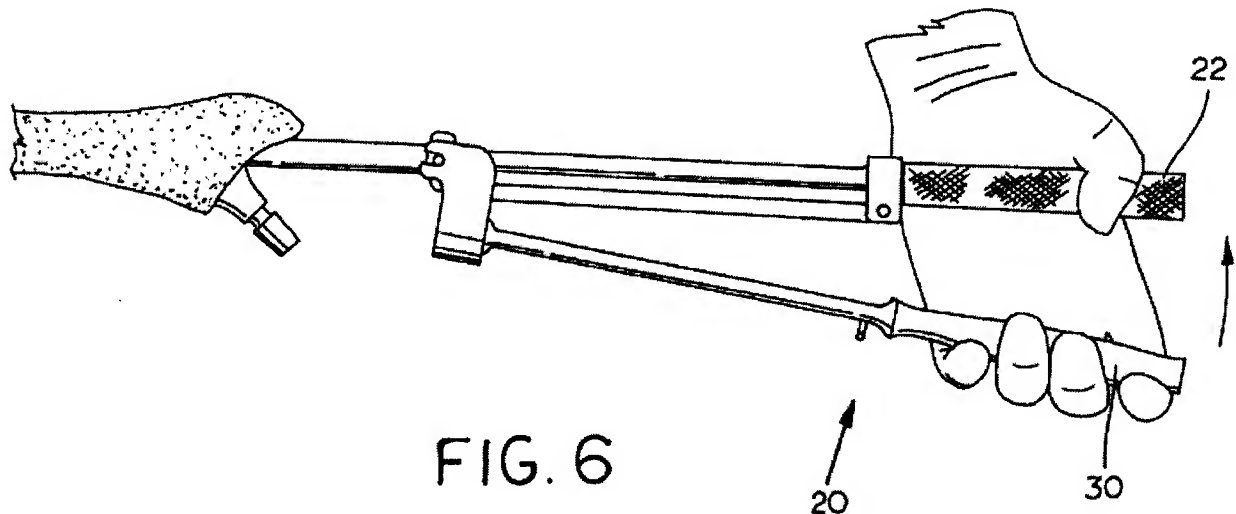
In response to this argument, the Office Action asserts that “a clamp is considered a device that holds a device to a certain orientation. Meulink et al. disclose a clamp portion as noted above wherein 50 and 40 work to secure the clamp, and its respective portions of the device in a relative position to one another.” This definition is contrary to the general understanding of the term clamp and is an unreasonable definition. A clamp is generally understood to be device for holding two or more components together by compressing, claspings, binding, constricting, or otherwise holding the components together. For example, Merriam-Webster’s online dictionary defines a clamp as follows:

- 1 : a device designed to bind or constrict or to press two or more parts together so as to hold them firmly
  - 2 : any of various instruments or appliances having parts brought together for holding or compressing something.
- (<http://www.m-w.com/dictionary/clamp>)

The Office Action’s definition of a clamp as merely “a device that holds a device to a certain orientation” is overly broad and unreasonable.

However, even under the unreasonable definition of a clamp set forth in the Office Action, let alone a reasonable definition, Meulink fails to disclose a clamp. The pivot block 36, as its name implies, is configured such that the pivot handle 30 can pivot or move about the fulcrum 40 with respect to stationary handle 22, as shown in Fig. 6 below. Thus, the pivot block 36 and its associated fulcrum 40 and connecting pin 50 do not hold the shafts 24, 33 or any other portion of the junction assembly tool 20 to a “certain orientation.” Rather, the pivot block 36, fulcrum 40, and connecting pin 50 are configured precisely to facilitate a change in orientation so that a mechanical advantage can be created. It is clear that the pivot block 36 is simply not a

clamp assembly even under the unreasonably broad definition set forth in the Office Action. Thus, even when combined Winslow and Meulink fail to teach all of the claimed elements of claim 20. Therefore, for at least this reason the Examiner's burden of establishing a prima facie case of obviousness has not been met. Applicants respectfully request that the §103(a) rejection of claim 20 be withdrawn.



Second, there is no reason for combining the pivot block 36 of Meulink with the method of Winslow. Recently, the Supreme Court ruled that the “teaching, suggestion, or motivation (TSM) test” still applies, but should be used in a more “expansive and flexible” manner. *KSR Int’l. Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 11 (2007). The Court stated that

“A patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 14-15, emphasis added.

In the present case, the Examiner has not expressed any reason why a person of ordinary skill in art would combine the pivot block 36 of Meulink with the method of Winslow. The Office Action stated that the reason would be to “better orient the alignment device relative to the prosthetic device.” However, the retractor 100 of Winslow includes a longitudinal opening or passageway (104) for receiving and guiding the insertion instrument 400. It is unclear how the pivot block 36 could be combined with the retractor 100 and its passageway 104 to better orient the alignment device to the prosthetic device as the prosthetic device is to go through the passageway 104. Further, the junction assembly tool 20 of Meulink is for providing a mechanical advantage in assembling multi-component prosthetic devices, not inserting a prosthetic device nor aligning a prosthetic device for insertion. There is no reason to combine aspects of the junction assembly tool 20 with the retractor 100 of Winslow, other than hindsight based on the present invention.

In this context, the PTO provides in MPEP §2143.01:

*The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.* (emphasis in original)

The courts have repeatedly held that obviousness cannot be established by combining the teachings of prior art references to produce the claimed invention absent some teaching, suggestion, motivation, or other reason supporting the combination. In the present case, it is clear that neither Winslow nor Meulink contain any such reason for supporting the combination recited in claim 20. The combination of Winslow and Meulink arises solely from hindsight based on the currently claimed invention. For at least this additional reason the Examiner’s burden of establishing a prima facie case of obviousness has not been met with respect to independent claim 20. Applicants respectfully request that the §103(a) rejection of claim 20 be withdrawn.

**Claim 21** stands rejected under 35 U.S.C. §103(a) as being unpatentable over Winslow in view of Meulink as applied to claim 20, and further in view of U.S. Patent No. 6,283,966 to

Houfburg (“Houfburg”). Claim 21 depends from and further limits claim 20. As noted above, however, Winslow and Meulink are insufficient to support a prima facie case of obviousness with respect to claim 20. Houfburg does not affect this deficiency. Thus, for at least the same reasons, even when combined Winslow, Meulink, and Houfburg cannot support a §103(a) rejection of claim 21. Therefore, the Examiner’s burden of factually supporting a prima facie case of obviousness has clearly not been met, and Applicants respectfully request that the §103(a) rejection of claim 21 be withdrawn.

Further, claim 21 recites, “wherein aligning the alignment instrument comprises aligning a radiographic marker disposed within the alignment instrument via a fluoroscopic machine.” However, Houfburg does not teach having a radiographic marker disposed within an alignment device. Rather, in the portion Houfburg cited by the Office Action, radiographic templating is discussed in the context of determining an appropriate implant size. There is simply no disclosure of a radiographic marker being disposed within an alignment instrument. Thus, Houfburg clearly does not teach aligning the alignment instrument by aligning a radiographic marker disposed within the alignment instrument as required. Therefore, even when combined Winslow, Meulink, and Houfburg fail to teach all of the recited elements of claim 21. Thus, for at least this additional reason the Examiner’s burden of factually supporting a prima facie case of obviousness has clearly not been met, and Applicants respectfully request that the §103(a) rejection of claim 21 be withdrawn.

**Claim 22** stands rejected under 35 U.S.C. §103(a) as being unpatentable over Winslow in view of Meulink as applied to claim 20, and further in view of U.S. Patent No. 6,302,890 to Leone, Jr. (“Leone”). Claim 22 depends from and further limits claim 20. As noted above, however, Winslow and Meulink are insufficient to support a prima facie case of obviousness with respect to claim 20. Leone does not affect this deficiency. Thus, for at least the same reasons, even when combined Winslow, Meulink, and Leone cannot support a §103(a) rejection of claim 22. Therefore, the Examiner’s burden of factually supporting a prima facie case of obviousness has clearly not been met, and Applicants respectfully request that the §103(a) rejection of claim 22 be withdrawn.

**Claims 23-29** stand rejected under 35 U.S.C. §103(a) as being unpatentable over Winslow in view of Meulink as applied to claim 20, and further in view of U.S. Patent No. 5,643,286 to Warner et al. (“Warner”). Claims 23-29 depends from and further limit claim 20 either directly or indirectly. As noted above, however, Winslow and Meulink are insufficient to support a prima facie case of obviousness with respect to claim 20. Warner does not affect this deficiency. Thus, for at least the same reasons, even when combined Winslow, Meulink, and Warner cannot support a §103(a) rejection of claim 22. Therefore, the Examiner’s burden of factually supporting a prima facie case of obviousness has clearly not been met, and Applicants respectfully request that the §103(a) rejection of claims 23-29 be withdrawn.

**CONCLUSION**

It is believed that all matters set forth in the Office Action have been addressed, and that all pending claims are in condition for allowance. Favorable consideration and an early indication of the allowance of the claims are respectfully requested.

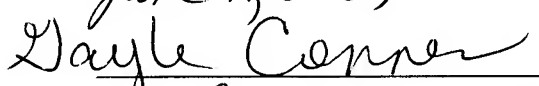
Should the Examiner deem that an interview with Applicants' undersigned attorney would expedite consideration of the elected claims, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

Respectfully submitted,



David M. O'Dell  
Registration No. 42,044

Dated: 6-1-07  
HAYNES AND BOONE, LLP  
901 Main Street, Suite 3100  
Dallas, Texas 75202-3789  
Telephone: 972-739-8635  
IP Facsimile No. 214-200-0853  
R-165814.1

Certificate of Service
I hereby certify that this correspondence is being filed with the U.S. Patent and Trademark Office via EFS-Web on
June 1, 2007

Gayle CONNER